

REMARKS

I. Claim Status

Claims 1-49 are currently pending. By way of this Amendment, claims 1, 35, 39-42, 44, 47, and 48 are canceled without prejudice or disclaimer or loss of Applicants' right to file the subject matter of these claims in continuation or divisional applications. Claim 2 has been amended to be in independent form and to incorporate the elements of canceled claim 1. Independent claims 2, 37, 38, 43, 46, and 49 have been amended to delete "anagrelide in base form" since "anagrelide" encompasses anagrelide in base form. Dependent claims 3-11, 13-17, 19-26, 28-31, 33, 34, and 36 have been amended to maintain proper antecedent basis, accordingly. Claims 1, 37, and 38 have been amended to replace "in a manner whereby first pass liver metabolism is avoided" with "in a manner avoiding first pass liver metabolism." Claims 3, 36, 43, and 46 have been amended to replace "skin permeable form of anagrelide..." with recitation of "with a skin permeation enhancer." Claim 18 has been amended to recite proper antecedent basis to a skin permeation enhancer. Claims 6, 10, 21, and 32 have been amended to correct typographical or grammatical errors. Claims 19 and 28 have been amended to delete "any optional" and "optionally," respectively. Claims 43 and 46 have been amended to replace "means for maintaining said reservoir in material transmitting relationship to the skin" with "an adhesive." Dependent claims 3-34, 36, and 45 have been amended to recite "The method/composition/device" instead of "A method/composition/device."

Therefore, upon entry of this Amendment, claims 2-34, 36-38, 43, 45, 46, and 49 will be pending.

Each of the amendments listed above are supported within the claims as originally filed. Therefore, no new matter is introduced by way of these amendments.

II. Restriction Requirement

The Official Action requires a restriction of the pending claims to one of the following seven claim groups:

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| Claim Group I: | Method for the treatment or prevention of thrombocythemia (claims 1-36); |
| Claim Group II: | Method of reducing the platelet count in a patient (claim 37); |
| Claim Group III: | Method of reducing side effects associated with oral administration of anagrelide (claim 38); |
| Claim Group IV: | Composition comprising anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide and at least one skin penetration enhancer (claims 39 and 40); |
| Claim Group V: | Composition comprising anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide and at least one adhesive (claims 41 and 42); |
| Claim Group VI: | Medical device for the transdermal administration of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide wherein the device is comprised of a skin permeable reservoir means containing a form of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide (claims 43-48); and |
| Claim Group VII: | Medical device for the transdermal administration of anagrelide, anagrelide in base form, or a pharmaceutically acceptable salt of anagrelide wherein the device is comprised of a backing layer, a release liner, and at least one anagrelide composition layer situated in between and one adhesive (claim 49). |

In addition, the Official Action requires an election of one of the following species within each species group below for claim Group I:

- Species Group A: Mode of administration – implants, sublingual, pregastric absorption, pessary, suppository, transdermal means, nasal spray, inhaled absorption, or topical means; and
- Species Group B: Associated diseases or conditions – essential thrombocythemia, chronic myelogenous leukemia, polycythemia vera, agnogenic myeloid metaplasia, and sickle cell anemia.

Finally, the Official Action requires an election of one of the following penetration enhancer subspecies should transdermal means within Species Group A be selected: linalool, carvacrol, thymol, citral, menthol, or t-anethole.

In order to be fully responsive, Applicants hereby elect, with traverse, Claim Group I, directed to a method for the treatment or prevention of thrombocythemia (claims 1-36; claims 2-34 and 36 upon entry of this Amendment); transdermal within Species Group A; essential thrombocythemia within Species Group B; and menthol within the subspecies group. Claims 2-9, 12-15, 17-34, and 36 read upon transdermal administration for the treatment or prevention of essential thrombocythemia using menthol as the skin penetration enhancer. Applicants note that claims 10 and 11 are directed to subdermal administration and claim 16 is directed to topical administration with an ointment, cream, or lotion.

Applicants note that upon the allowance of a generic claim, the Examiner will consider claims to additional species which depend or otherwise require all of the limitations of the allowable generic claim.

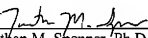
Applicants respectfully traverse the Requirement and reserve the right to petition therefrom under 37 C.F.R. 1.144. In particular, Applicants respectfully request that the Requirement for Restriction be withdrawn, so that all of the pending claims may be examined together in this application. Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims directed to distinct or individual inventions." *See*, M.P.E.P. § 803. The groups of claims designated in this Official Action are inter-related as directed to methods and compositions for administration of anagrelide to avoid first pass liver metabolism. They do not, therefore, define methods or compositions which are sufficiently distinct to warrant separate examination and searches. Indeed, each of the seven Claim Groups is identified by the Examiner to be within the same search class (514) and subclass (266.220).

For the foregoing reasons, Applicants respectfully request that the Requirement for Restriction be withdrawn, and that claim groups be rejoined and examined together in this application.

The Examiner is encouraged to contact the undersigned by telephone at the number listed below in the event that she believes further amendment to the claims may facilitate the reconsideration of this application.

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Respectfully submitted,

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